REMARKS

This is in response to the Office Action dated March 13, 2008. Claims 1-13 are pending. Applicant would like to thank the Examiner for the courtesy extended during the interview held on February 17, 2009. At the interview, it was explained that the claims define over the cited art for the reasons explained herein.

Claim 1

Claim 1 stands rejected under 35 U.S.C. Section 103(a) as being allegedly unpatentable over Smits (US 4,641,656) in view of Alferness (US 6,169,922). This Section 103(a) rejection is respectfully traversed for at least the following reasons.

Claim 1 requires "wherein the single electrode of the quasi-Faraday cage is adapted to be wrapped around at least about 50% of the heart during application of electric shock to the heart, so that electric shock is applied to the heart between the quasi-Faraday cage and said electrode of the ICD located inside of the heart to make the shock less painful as the conductive quasi-Faraday cage is shaped and provided so that most of a defibrillation shock field is confined to the heart itself so as to prevent the shock from significantly stimulating extracardiac tissue." It is noted that a quasi-Faraday cage does not cover any merely sort of jacket; instead, a quasi-Faraday cage comprises a *conductor* that encloses a majority of the interior volume of the heart. Thus, in certain example embodiments, a quasi-Faraday cage shields a region outside the cage from electric fields generated inside (and/or vice versa). Claim 1 expressly requires that, *due to the shape of the conductive quasi-Faraday cage, most of a defibrillation shock field is confined to the heart itself so as to prevent the shock from significantly stimulating extracardiac tissue.* The cited art fails to disclose or suggest the aforesaid underlined features of claim 1, either alone or in combination.

Smits in Figs. 24-26 shows that much of the shock field is *outside* of the heart. This is because there is no quasi-Faraday cage in Smits to prevent most of the shock field from leaving the heart. It is this shock field external the heart which is problematic, as it causes significant pain to patients. The invention of claim 1 expressly provides that a conductive quasi-Faraday cage is provided and shaped so that most of the shock field is confined to the heart itself – both Smits and Alferness fail to disclose or suggest this subject matter. Thus, even the alleged combination (which would be incorrect in any event) fails to meet this important feature of claim 1. A more detailed explanation is provided below as to why even the alleged combination fails to meet claim 1.

Termination of ventricular fibrillation, known as defibrillation, is achieved by applying a brief high-voltage electric field across most of the ventricular myocardium. The prior art, including Smits (4,641,656) and Alferness (6,169,922) teach defibrillation using electrode configurations that apply dipole (or more complex) fields to the heart, but do so without providing a means for confining the electric field mostly to the heart. As a result, the defibrillation shocks delivered by the Smits and Alferness devices result in electric fields that encompass the heart and a great deal of non-cardiac tissue, such as muscles and nerves in the chest and abdomen, as well. When these extra-cardiac tissues are exposed to this high-voltage electric field in Smits and Alferness, the patient experiences enormous pain. In Smits, Figs. 24-26 show that a shock using the Smits electrode arrangements results in an electric field pattern that extends well beyond the cardiac tissues. Smits teaches electrode configurations that apply either dipole or quadripolar electric fields, but in all cases, the significant field lines extend well outside the borders of the heart. Furthermore, the outermost field ring shown in Figs. 24-26 by no means represents the full extent of the applied field, but rather just the shape of the electric

field at that distance from the electrodes. Thus, Smits teaches the opposite of what claim 1 requires, thereby teaching away from the invention of claim 1.

Alferness teaches the use of a non-conductive jacket placed around the heart, but the only electrode arrangement taught in Alferness is that of two electrodes of opposite polarity applied to opposite sides of the ventricles. Electrically, this produces a simple dipole field that extends both inside and outside the heart – like that in Smits. As in Smits, this electric field in Alferness cannot avoid stimulating extra-cardiac tissue. In contrast, claim 1 requires the use of a quasi-Faraday cage that maintains a fixed electric potential at the border of the heart, while a defibrillation shock is applied between this outer electrode and a separate electrode placed within a ventricular chamber. This arrangement applies a dipole field across the ventricular myocardial tissues, but prevents leakage of any significant electric field outside the heart border, thereby shielding extra-cardiac tissues from the shock. This provides a defibrillation shock that produces substantially reduced pain. Smits and Alferness each teach away from electrode arrangements that would confine the electric field to mainly within the heart border. Even if combined, Smits and Alferness together still do not teach any structure that would yield a single cage electrode or even the effect of a single electrode surrounding the heart. Thus, any device taught by Smits and Alferness, individually or combined, would deliver defibrillation shocks that would stimulate significant extra-cardiac tissue and produce substantial pain. In other words, both Smits and Alferness fail to disclose or suggest a conductive quasi-Faraday cage that is shaped and provided so that most of a defibrillation shock field is confined to the heart itself so as to prevent the shock from significantly stimulating extracardiac tissue. Even the alleged combination fails to meet claim 1.

Heilman is flawed for the same reasons as Smits and Alferness. Thus, citation to Heilman does not cure the flawed discussed above with respect to Smits and Alferness.

Claim 4, 8, 12 and 13 require that the quasi-Faraday cage is shaped and provided so that most of a defibrillation shock field is confined to the heart itself thereby preventing the shock from significantly stimulating extracardiac tissue. The cited art to Smits, Heilman and Alferness fails to disclose or suggest this, either alone or in combination.

It is respectfully requested that all rejections be withdrawn. All claims are in condition for allowance. If any minor matter remains to be resolved, the Examiner is invited to telephone the undersigned with regard to the same.

Respectfully submitted,

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